

PETER A. DEFazio
4TH DISTRICT, OREGON

RESOURCES COMMITTEE

SUBCOMMITTEE:
FISHERIES CONSERVATION,
WILDLIFE AND OCEANS

TRANSPORTATION AND
INFRASTRUCTURE

SUBCOMMITTEES:
AVIATION
COAST GUARD AND
MARITIME, RANKING



Congress of the United States

House of Representatives

April 4, 2000

PLEASE RESPOND TO:

- ☐ 2134 RAYBURN HOUSE OFF. BLDG.
WASHINGTON, DC 20515-3704
(202) 225-6416
- ☐ 151 WEST 7TH AVE. #400
EUGENE, OR 97401-2649
(541) 465-6732
1-800-944-9603
- ☐ P.O. BOX 1557
COOS BAY, OR 97420-0333
(541) 269-2609
- ☐ P.O. BOX 2460
ROSEBURG, OR 97470-0511
(541) 440-3523
- ☐ Peter.DeFazio@mail.house.gov

PRESENTATION AT FDA PUBLIC MEETING

My name is Peter DeFazio. I am a member of Congress from Oregon's fourth congressional district. I have been a close observer of the Food and Drug Administration's treatment of dietary supplement health claims for many years and I am here to voice my concerns about FDA's resistance to follow Congress' direction on the labeling claims of dietary supplements.

FDA's history of regulating dietary supplements has been one long legacy of suppression. Despite extraordinary research findings in nutritional science over the past four decades, FDA has authorized only three health claims for dietary supplements. On three occasions in 1990, in 1994, and again in 1998, Congress approved legislation designed to allow consumers greater access to information on the health claims of dietary supplements. Each time their efforts have been thwarted by resistance from this agency. Despite statutory law to the contrary, FDA has refused to authorize health claims that are backed by sound scientific evidence.

I appear today to voice my concerns about FDA's continuing resistance to the will of Congress. I am also deeply concerned by FDA's failure to implement the constitutional order of the United States Court of Appeals for the D.C. Circuit in *Pearson v. Shalala*. The court held that FDA could not constitutionally deny a health claim that conveyed information, but instead would be required authorize the claim accompanied by a reasonable disclaimer.

On January 15, 1999, the Court held four onerous FDA rules regarding dietary supplement health claims unconstitutional under the First Amendment. Now, over fourteen months later FDA still has not implemented the Court's mandate to allow certain health claims. Indeed, this public meeting is yet further evidence of the administrative delays that plague agency compliance with the direct order of the Court.

I urge FDA to implement the Court's mandate without any further delay. The unconstitutionally denied claims should be immediately authorized. FDA has had over nine years to evaluate the claims. FDA has had ample time to consider disclaimers. Indeed, the Court has supplied you with five specific types of disclaimers it finds acceptable. There simply is no excuse for not following the law without delay.

Congress' patience is running thin. We have asked FDA to give consumers the health claim information they need to exercise informed choice in the market. FDA has yet to implement the court's mandate. Let me be clear: FDA is not above the law. We do expect FDA to implement promptly fully and faithfully the decision of the United States Court of Appeals. Thank you.

00N-0598

TS / 5